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## **Q and A on the Harvard Center for Risk Analysis study of BSE.**

### **Q. What does this study say about the risks of BSE in the United States?**

A. The study finds that in the unlikely event that BSE were to be introduced into the United States, control measures already in place insure that either zero or very few additional animals would get sick, and the disease would eventually die out.

### **Q. Has BSE ever been found in the United States?**

A. BSE has not been diagnosed in the United States.

### **Q. What about the risk to humans?**

A. The study finds that if sick cattle were imported into the U.S. cattle herd, very few additional animals would get sick. Thus, there is a low likelihood that any human cases of variant Creutzfeldt Jacob disease, the human disease believed to be caused by BSE, would result from a U.S. source.

### **Q. How can the researchers say these things? How did they come up with these findings?**

A. USDA hired the Harvard Center for Risk Analysis to do an independent study of what would happen if BSE got into America. The study team learned about the biology of BSE and vCJD. They went to Europe and studied what happened there, particularly in the United Kingdom. They also traveled to farms and slaughterhouses and processing plants in America, to learn about the animal agriculture industry here at home. They studied American regulations that are supposed to deal with BSE, including levels of compliance (or noncompliance) with those regulations.

Based on three years of study of the issue, they constructed different hypothetical scenarios that explored how BSE might get into America. Since there are no reported cases here so far, the researchers supposed for these scenarios that either 1, 5, 10, 20, 50, 200, or 500 sick cattle were imported into the United States. (That would be illegal under current regulations, but the team assumed it might happen so they could test what would happen next.) They built a computer model and ran 1,000 variations for each of their main scenarios.

Some of their scenarios looked at what would happen if the disease were introduced starting today. Some of them looked at situations in which the disease might have already been introduced *before* government restrictions on importation of sick animals.

### **Q. Tell me more about the specifics of what they found.**

A. The analysis found that because of the FDA's feed ban, which keeps ruminant parts from being rendered and used in feed that goes back to healthy cattle, in every single scenario they test, too little of the BSE that gets into the American herd goes from sick animals to healthy ones to perpetuate the outbreak. That's the way most scientists think the disease became an epidemic in England, and spread to other animals in other countries. The report finds that even with current incomplete levels of compliance with the feed ban, that kind of epidemic almost certainly can not occur.

**Q. The report talks about cattle being exposed to ID50s. What are these?**

A. A cattle oral ID50 is the amount of infectious tissue that would on average cause 50% of cattle exposed to develop BSE. Another way to look at this is, if a cow is fed one oral ID50, she has a 50% chance of becoming affected. ID50s are measurements that allow the researchers to keep track of how much of the agent is in different parts of the animal.

**Q. So, what is the risk?**

A. Nobody can ever say there is absolutely zero risk. But let's look at the worst case these experts could think of—the illegal and undetected importation of 500 sick animals.

They found that only an additional 460 animals in America would get sick, out of a herd of approximately 100 million, and the disease would die off and be gone in about 20 years. (And remember, that's the very worst case scenario, and pretty unlikely to happen.)

It's more likely that one animal gets in, or five, or ten, and in nearly all of those scenarios, the most likely outcome is that NO additional animals get sick, or maybe just one or two.

**Q. How about risks to humans?**

A. The report says human exposure to BSE would be low if the disease were present in the US, but it cannot put a precise number on the risk. Here's why.

The researchers can predict how many animals might get sick. They also know that the parts of the animal believed to carry the disease to humans are the brain, spinal cord, and some parts of the central nervous system. The disease is not believed to be transmitted by meat, fat, bone, or many other parts of the animal.

Based on information from industry and the USDA, the researchers estimated how much of this brain and spinal cord might be in human food. But there's one thing they can't measure. There's no way to know how much of this material people actually eat. Without that actual measure of real-life exposure, they can't make any kind of specific prediction about human cases. That's why it is characterized as potential human exposure.

The researchers can calculate how many of these cattle oral ID-50s may get into the human food supply. And they can compare that to how many of these units got into the human food supply in the UK, where there have been approximately 100 cases of vCJD so far.

It's estimated that in the UK, several million of these cattle oral ID-50s probably got into the human food supply. The Harvard report found that if BSE got into the American herd, in the most likely scenario to occur, where just one sick animal gets in, only a total of 6 cattle oral ID-50s would get to the food supply, *over 20 years*. In their very worst case scenario, in which 500 sick cows somehow get in, only a total of 3400 cattle oral ID-50s get to human food over 20 years, just 170 a year on average.

So based upon what we know about how much it takes to transmit the disease from animals to humans, and what we know of what happened in the UK, the chances of a human case are low.

**Q. Are there other ways besides infected cattle for BSE to get into America? Does this study take that into account?**

A. Yes. Harvard also considered spontaneous occurrence of BSE as well as scrapie, chronic wasting disease, and other cross-species transmission of similar diseases—but the important thing is how it would spread if it were introduced. Remember, the way scientists think the disease spreads is through the rendering of diseased animal parts into cattle feed that is fed back to healthy animals. So it doesn't really matter how it gets in. The researchers used live animals as a vector, a carrier, but they could just as well have used meat and bone meal or any other possible source. They just studied current U.S. agricultural practices to see if or how it would spread, no matter what the original source. Again, the existing feed ban chokes the disease off and keeps it from becoming a serious threat to animal or human health.

**Q. But what about reports I've heard that there are violations of that feed ban?**

A. The report assumes those violations. In fact, their hypothetical scenarios it assume that even after BSE is detected in America, that government regulations and enforcement stay the same and some violations continue to occur. It takes that incomplete compliance into account.

**Q. Does the report address the possibility that some infected cattle got into America before we started banning cattle from countries that have BSE?**

A. The report specifically considered the 334 cattle that came into America from the UK, where the disease was worst, from 1980 until the ban on imports from the UK in 1989. They found an 80% chance that cattle in the United States were not exposed to BSE from the U.K. imports. It's likely the U.K. imports were not infected with BSE in the first place, for three reasons.

- They were beef animals, and those types of cattle received much less animal protein feed than most of the animals that became sick.
- They came from farms where NO cattle born the same year got sick, another sign that infection wasn't around.
- About half the cattle were tracked in America until death and we know they were disposed of in a way that prevented any spread of disease, if the disease had been present. The other half were known to be healthy for years after coming to America. That's long past the incubation period, typically four to six years, for BSE.

But even if U.S. cattle were exposed to BSE from these imports, it is unlikely that a lot of cattle would have become sick because if a lot of cattle had become sick, it is very likely that they would have been detected by USDA. Finally, if BSE were introduced into the United States, the Harvard analysis shows that, because of the FDA feed ban, its prevalence would now be on the decline, and that it eventually would be eradicated.

**Q. Does that mean there's a 20 percent chance that BSE is in the U.S. already?**

A. No. It only means that there was a 20 percent chance that cattle in the United States were exposed to BSE from these imports. Even if they were exposed, there is a significant chance that the exposure caused no cases of BSE in U.S. cattle.

**Q. What about the possibility of BSE coming from other sources that are already here such as elk with chronic wasting disease or the practice of feeding cattle parts to pigs?**

A. The report looked at the science for what is called 'cross-species transmission' and found that it's unlikely to happen. But even if it does, the report says that so little of it could happen that again, a very small number of additional cattle might get sick, and the risk to humans from this source would also be extremely low.

**Q. The report states that in an extreme case, characterized using the 95th percentile of the output distribution from the simulation, the import of 10 animals leads to only 11 new cases of BSE over 20 years. What does this mean?**

A. The introduction of 10 known infected cattle into the United States was a hypothetical situation to investigate what would happen. The 95th percentile is used to characterize the worst case for what may happen if these infected cattle came in, because it's very unlikely that the reality would be any worse. Hence, it is very unlikely that more than 11 new cases would result over 20 years.

**Q. How does this relate to people and what the public is exposed to?**

A. The relationship between what infectivity people are exposure to, quantified in terms of cattle oral ID50s, and the likelihood of human disease is unknown. However, European authorities suggest that the cattle disease may be 10 to 100,000 times less virulent in humans.

**Q. Can USDA guarantee that BSE will not occur in the United States?**

A. Given the many unknowns about the disease, including its exact origin, we cannot say the disease will never occur. However, the Harvard analysis has found that we are highly resistant to an introduction of BSE and measures taken by the U.S. government and industry make our system resistant against the spread of BSE to animals and humans, should it occur in this country. Although the risk is already low, USDA will use this study to guide us in taking actions to which will reduce risk even further.

**Q. Does this means there is a risk for me?**

A. USDA cannot guarantee zero risk, but our goal is to bring the risk as close to zero as possible.

**Q. What will the USDA do in response to the study?**

A. Using the results of the study, the USDA will examine ways to further limit the exposure of the public and cattle to BSE if present in the country. These will include: prohibiting the use of brain and spinal cord from specified cattle in human food; prohibiting the use of central nervous system tissue in boneless beef products, including meat from advanced meat recovery systems; and prohibiting the use of the vertebral column from certain categories of cattle, including downed animals, in the production of meat from advanced meat recovery systems. We will invite public comment on any options and then proceed with appropriate regulatory actions.